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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---|---|---|---|---|
| 09/940,422 | 08/29/2001 | Lorraine Mary Edmeades | 1430-272 | 5500 |

23117 7590 03/11/2005

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| EXAMINER | |
|---|---|
| SODERQUIST, ARLEN | |

| ART UNIT | PAPER NUMBER |
|---|---|
| 1743 | |

DATE MAILED: 03/11/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

| **Advisory Action Before the Filing of an Appeal Brief** | **Application No.** 09/940,422 | **Applicant(s)** EDMEADES ET AL. | |
|---|---|---|---|
| | **Examiner** Arlen Soderquist | **Art Unit** 1743 | |

***--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --***

THE REPLY FILED 28 February 2005 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE.

1. ☐ The reply was filed after a final rejection, but prior to filing a Notice of Appeal. To avoid abandonment of this application, applicant must timely file one of the following replies: (1) an amendment, affidavit, or other evidence, which places the application in condition for allowance; (2) a Notice of Appeal (with appeal fee) in compliance with 37 CFR 41.31; or (3) a Request for Continued Examination (RCE) in compliance with 37 CFR 1.114. The reply must be filed within one of the following time periods:
   a) ☐ The period for reply expires _____months from the mailing date of the final rejection.
   b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection.

   Examiner Note: If box 1 is checked, check either box (a) or (b). ONLY CHECK BOX (b) WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

NOTICE OF APPEAL

2. ☒ The reply was filed after the date of filing a Notice of Appeal, but prior to the date of filing an appeal brief. The Notice of Appeal was filed on *28 February 2005*. A brief in compliance with 37 CFR 41.37 must be filed within two months of the date of filing the Notice of Appeal (37 CFR 41.37(a)), or any extension thereof (37 CFR 41.37(e)), to avoid dismissal of the appeal. Since a Notice of Appeal has been filed, any reply must be filed within the time period set forth in 37 CFR 41.37(a).

AMENDMENTS

3. ☐ The proposed amendment(s) filed after a final rejection, but prior to the date of filing a brief, will not be entered because
   (a) ☐ They raise new issues that would require further consideration and/or search (see NOTE below);
   (b) ☐ They raise the issue of new matter (see NOTE below);
   (c) ☐ They are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
   (d) ☐ They present additional claims without canceling a corresponding number of finally rejected claims.

   NOTE: _____. (See 37 CFR 1.116 and 41.33(a)).
4. ☐ The amendments are not in compliance with 37 CFR 1.121. See attached Notice of Non-Compliant Amendment (PTOL-324).
5. ☐ Applicant's reply has overcome the following rejection(s): _____.
6. ☐ Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).
7. ☒ For purposes of appeal, the proposed amendment(s): a) ☐ will not be entered, or b) ☒ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.
   The status of the claim(s) is (or will be) as follows:
   Claim(s) allowed: _____.
   Claim(s) objected to: _____.
   Claim(s) rejected: *12,14 and 15*.
   Claim(s) withdrawn from consideration: _____.

AFFIDAVIT OR OTHER EVIDENCE

8. ☐ The affidavit or other evidence filed after a final action, but before or on the date of filing a Notice of Appeal will not be entered because applicant failed to provide a showing of good and sufficient reasons why the affidavit or other evidence is necessary and was not earlier presented. See 37 CFR 1.116(e).
9. ☐ The affidavit or other evidence filed after the date of filing a Notice of Appeal, but prior to the date of filing a brief, will not be entered because the affidavit or other evidence failed to overcome all rejections under appeal and/or appellant fails to provide a showing a good and sufficient reasons why it is necessary and was not earlier presented. See 37 CFR 41.33(d)(1).
10. ☐ The affidavit or other evidence is entered. An explanation of the status of the claims after entry is below or attached.

REQUEST FOR RECONSIDERATION/OTHER

11. ☒ The request for reconsideration has been considered but does NOT place the application in condition for allowance because:
    See Continuation Sheet.
12. ☐ Note the attached Information Disclosure Statement(s). (PTO/SB/08 or PTO-1449) Paper No(s). ____
13. ☐ Other: _____.

Arlen Soderquist

ARLEN SODERQUIST
PRIMARY EXAMINER

Continuation of 11. does NOT place the application in condition for allowance because: for the reasons of record and the following additional comments. First, Examiner points to a few additional sections of the instant specification in combination with those already cited in the explanation of the anticipation by Floyd (pages 2-3). The first of these sections of the instant specification is found on page 6, lines 6-8 and is repeated below.

"Pharmaceutical dosage forms, which include conventional oral tablets and dispersible tablets, are therefore typically assayed for compound A only."

This section defines the phrase "pharmaceutical dosage forms" by non-limiting examples through the use of the word "include". The other important part of this sentence is the "dispersible tablets" which would constitute as near as examiner can tell some form of the medicine that was at least partially dissolvable prior to being administered. The next section of the instant specification is the last paragraph of page 21 which is reproduced below.

"The present invention has been described by way of example only, and it is to be recognised that modifications thereto which fall within the scope and spirit of the appended claims, and which would be obvious to a skilled person based upon the disclosure herein, are also considered to be included within the invention."

It is clear from this statement that applicant does not wish to be limited by the words or examples used in the specification. As such it is not proper to read into the claims a specific limitation from the specification when the specification does not define that limitation in a closed manner. As a result examiner is correct in using a definition of "solid pharmaceutical dosage form" that is inclusive of the lyophilized (solid) dosage form of the Floyd references. If applicant were to limit the solid pharmaceutical dosage form to the group consisting of oral tablets and dispersible tablets, there might be some validity to the argument. But this would cause new considerations that haven't happened at this point relative to the anticipation or obviousness of these specific dosage forms in view of the disclosure of Floyd. Since Floyd is anticipatory, the secondary references are fully adequate for showing the obviousness of the additional limitations in claims 14-15 .